

K950972

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510 (k) Summary

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Device Name: TSXF-001A

Common Name: Real-Time Reconstruction System Option for Xpress/SX
CT System

Classification Name: Computed Tomography X-Ray System

Classification: Class II

Establishment Reg. Number: 2020563

Predicate Device: TSX-011A (Xpress CT System) [Toshiba Corp.]

Description of this device: The TSXF-001A is an optional upgrade kit available for the Xpress/SX CT system (TSX-011A/50). The kit consists of hardware and software that can be field installed by a qualified Field Service Engineer. When equipped with this option, the Xpress/SX system will have the capability to reconstruct and display axial slices at the rate of six images per second, effectively emulating a real-time display presentation. Additionally, an added control panel provides table-side control of x-ray initiation and termination, table longitudinal and vertical motion, and gantry tilt.

Intended use of this device: Computed Tomography X-Ray Scanners generally support three modes of imaging:

- 1) Multiple contiguous slices: conventional CT where individual slices of axial data are acquired, with the table advancing a set distance until a volume of interest is covered.
- 2) Helical Scanning: a volume of interest is scanned continuously while the patient table is advanced longitudinally, until a desired volume of data is acquired.
- 3) Dynamic scanning: a single slice location is scanned repeatedly over a period of time.

Using the Real-Time Reconstruction System (RTRS) Option, the scanner effectively operates in the dynamic scan mode with the added flexibility of table and/or gantry movement during scanning. Under the control of the operating physician the RTRS is intended to speed up interventional procedures typically performed on CT. By permitting the operator to view the scanned area in virtual real time the RTRS is intended to support existing CT system clinical uses by offering enhanced

operator flexibility coupled with the potential of reduced scan time.

Features included with the RTRS to help control patient radiation dose are:

- 1) Use of an attenuating filter which is moved automatically into the x-ray beam when the RTRS mode is selected.
- 2) Automatic interruption of scanning after a maximum period of one hundred seconds.
- 3) Display of the elapsed scan time on the in-room viewing monitor.

Comparison to predicate device: The Xpress/SX with Real-Time Reconstruction System option is an upgraded version of the predicate, the Xpress CT System. The enhancements of the Xpress/SX with RTRS include a larger x-ray generator, faster reconstruction time, a solid-state x-ray detector, and real-time reconstruction capabilities. Taken together, these features provide user flexibility and improvements to the efficiency with which the system is utilized. There are no perceived or imagined new intended uses for CT introduced by the Xpress/SX with RTRS option and the safety and effectiveness of the system are believed to remain within the accepted boundaries for this modality.